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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/802,314 | 03/17/2004 | Van Le Huynh | ECV-5539CON | 3894 |

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Irvine, CA 92614

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| EXAMINER |
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PELLEGRINO, BRIAN E

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| ART UNIT | PAPER NUMBER |
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3738

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03/20/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--|-------------------------------------|--|
| Office Action Summary | Application No. 10/802,314 | Applicant(s) HUYNH ET AL. | |
| | Examiner Brian E. Pellegrino | Art Unit 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8,11-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Totten et al. (4477930). Totten et al. disclose a tubular fabric with a stent frame and a ring insert, see Figs. 1, 6, 7, and col. 4, lines 8-11. Claims in a pending application should be given their broadest reasonable interpretation, *In re Hyatt*, 54 USPQ 2d 1664 (Fed. Cir. 2000). Therefore, the Totten suture ring is configured to pivot or moveable between two positions since it is made of an elastomer, col. 4, lines 12,13, and Fig. 8 illustrates that the sewing ring can pivot about the edge. Totten discloses the sewing ring to be pliable or suture permeable (col. 4, line 16), thus it can be interpreted to be bi-stable because of its flexibility and placement at a seam or edge as seen in Fig. 8. The ring can be considered “**generally** frusto-conical” as seen in Figs. 7,10. Totten also discloses the fabric covers the ring and connects the ring to the stent periphery at a seam, col. 5, lines 12-17. Fig. 8 also shows the insert ring to be “substantially planar.

Claims 1-7,11-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Vanney et al. (5843179). Vanney et al. disclose heart valve with a generally annular stent frame (Fig. 15C) and a ring insert, see Figs. 6A, 7A,9A. Claims in a pending application should be given their broadest reasonable interpretation, *In re Hyatt*, 54 USPQ 2d 1664 (Fed. Cir. 2000). Since the ring is covered (col. 11, lines 16,17) with fabric it is suture-permeable. Vanney discloses the ring is configured to pivot or

moveable between two positions i.e. (movement toward the inflow, Figs. 6B,7B,9B) since it is made of an elastomer, col. 10, lines 27-33. It can be interpreted to be bi-stable because of its flexibility and placement at a seam or attachment line, col. 10, lines 61-66. Fig. 15D shows the ring being planar. Vanney additionally discloses that the fabric can cover both the ring and a portion of the heart valve, col. 10, lines 54,55.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 9 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Totten '930 in view of Huynh et al. (5928281). Totten is explained supra. However, Totten does not disclose alternating thick and thin regions in the insert ring. Huynh teaches (Figs. 27, 32) that an insert ring for a suture ring is provided with thick and thin regions. It would have been obvious to one of ordinary skill in the art to use thick and thin regions as taught by Huynh in the sewing ring of Totten such that it provides more stability in maintaining the fabric covering to the ring.

Claims 10,21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Totten '930 in view of Reichart et al. (4626255). Totten is explained supra. However, Totten does not disclose the insert ring with a radially undulating shape. Reichart et al. teach (Fig. 1) that the sewing ring has an undulating shape. It would have been obvious to one of ordinary skill in the art to use the undulating shape for the sewing ring as

taught by Reichart with the heart valve of Totten in order to more closely match the shape of the natural annulus to where the prosthetic valve is being implanted.

Response to Arguments

Applicant's arguments filed 12/20/07 have been fully considered but they are not persuasive. First the Applicant's argue the rejection over the patent to Totten '930 and state it does not have a sewing ring configured to pivot between two positions, yet fails to structurally define how the claimed invention is different from the prior art. The Totten sewing ring is clearly capable of pivoting between two positions and would be stable in the first or second positions the sewing can be considered bi-stable. The Applicants provide no arguments as to why the sewing ring of Totten is not considered to be bistable and does pivot about an edge as seen in the drawing (Fig. 8). It should also be noted that claims 1 and 11 recite functional language "configured to pivot wherein the first and second positions are stable" is not given much patentable weight since it is not supported by sufficient structure to warrant the presence of the functional language or recitations in the claim of giving meaning to pivotable feature being stable. It can be said that the sewing ring of Totten pivots and is stable since it has an edge to cause the configuration to change directions.

Applicants additionally argue that the rejection over Vanney '179 stating the device is not a sewing ring. However, it should be noted that the claims recite the ring is suture-permeable of which Vanney's suture guard is fully capable of being suture permeable. Applicant argues claims 1 and 11 pertain to the entire sewing ring, of which

is not in the claim, but does not even explain what defines the "entire ring" from point to point. Second the Applicants argue that the suture-permeable guards do not pivot toward both inflow and outflow ends. However, the Examiner would like to note that the claims 1,11 only recite the pivoting to be "generally towards" and thus any change or pivoting away from one end to some degree towards the other end can be considered to meet the claim. Applicants lastly argue that the suture ring of Vanney is not bi-stable. However, the Examiner would like to note that the Applicants are mistaken since the Vanney ring can be stable in an open and closed position, it is bistable.

The remaining dependent claims rejected for additional features were not argued that they failed to teach the claimed limitation, other than stating they believed the independent claim was not met. Thus, these rejections are maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738